

This document answers frequently asked questions about the Pfizer and BioNTech Vaccine Decision Announcement on the 3 February 2021

**This information applies from 3 February 2021**

Information can be used for any government, agency, local government or relevant sector and business communications.

This is a living document that will be updated frequently over early January. Information that changes or is added between versions will be **highlighted**.

Please ensure you are using the most up to date version.

This version was current at **3.30pm, 3 February 2021**.

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## When will the vaccines arrive in New Zealand?

We expect the first vaccines will arrive in New Zealand by the end of the first quarter of the year, but we are making sure everything is in place in case of an earlier arrival. We have broadly similar timing expectations as Australia. We acknowledge there is international pressures for Pfizer and BioNTech to prioritise countries that have serious community transmission of COVID-19.

As we have seen, timelines are changing frequently. Specifically, we are in discussions with Pfizer and BioNTech about the impact of the EU's restrictions on New Zealand's vaccine delivery timing.

## When will the vaccination programme begin?

We do not have a confirmed date for our programme to begin but based on our current situation of no community transmission, our first focus will be vaccinating our border and managed isolation and quarantine workforce and their close contacts within the first quarter of this year. Once the vaccine arrives in New Zealand, we expect to be able to complete vaccinating this group within two to three weeks.

Our sequencing of who we vaccinate first only changes if our situation changes, such as if we have widespread community transmission. We expect to start vaccinating the general public in the second half of this year.

## Who will be vaccinated first?

Our first focus will be vaccinating our border and managed isolation and quarantine workforce and the people they live with. These frontline workers have been protecting our country from this global pandemic during the past year and protecting them, and those who share their households, is a priority for us.

Once the vaccine arrives in New Zealand, we expect to be able to complete vaccinating this group within two to three weeks.

Those covered by the [COVID-19 Public Health Response \(Required Testing\) Order 2020](#) will be the first people to be offered vaccinations and within that group, we will first offer vaccinations to those who are tested most frequently – those tested weekly.

After workers covered by the testing order are offered vaccinations, we will offer vaccinations to the people they live with.

## **Why are you vaccinating border workers first?**

We've always known that our greatest risk of COVID-19 entering New Zealand is at our border because the virus is rampant in many countries overseas, which is why we've put such tight measures in place at our border.

Protecting people working at the border and those at greatest risk of COVID-19 protects our entire population and adds another layer to our border defences.

Our sequencing of who we vaccinate first only changes if our situation changes, such as if we have widespread community transmission.

These frontline workers have been protecting our country from this global pandemic during the past year and protecting them and those who share their households is a priority for us.

## **When will you start vaccinating everyone?**

The confirmed timing of the rollout will depend on when the suppliers can deliver it. Our first focus will be to vaccinate our border and managed isolation and quarantine workers, around 12,000 people, plus the people they live with.

We expect to make vaccines available for the general public in the second half of the year. However, if vaccines become available earlier, we would look to move as soon as possible to begin a wider roll out.

## **Where will the first vaccinations of the general public be done?**

Initial delivery settings are likely to be workplace and some community locations. We are engaging with DHBs on their local plans for the initial scenarios, including the providers they are likely to engage. As more vaccines become available, we will add new settings as we scale up throughout the year.

## **What's the process for approving the vaccines?**

Medicines regulator Medsafe sought advice and recommendations from the Medicines Assessment Advisory Committee (MAAC) about the Pfizer and BioNTech vaccine.

The Ministerial expert advisory committee reviewed Medsafe's benefit-risk assessment of the pharmaceutical company's data, enabling Medsafe to grant provisional approval.

## How was approval decided?

We have been working with Pfizer for a number of months now and started receiving clinical data from the company in November. We streamlined the assessment process so the company could submit rolling data to us as it came through — rather than sending us all the data at the very end. This is the same for all the COVID-19 vaccines.

Allowing rolling submissions means we can streamline our assessment process without compromising the rigour of the requirements and safety of the vaccine.

It's important people understand we haven't cut any corners in the assessment along the way while we worked to make a decision.

Medsafe considered its feedback and decided to grant provisional consent, which includes conditions that require the pharmaceutical company to provide data and information within an agreed timeframe. This includes additional clinical trial and manufacturing data as it becomes available. The company agreed to these required conditions and Medsafe formally gazetted the decision to approve the vaccine's provisional consent for use in New Zealand.

## Who is on the Medicines Assessment Advisory Committee?

This committee is made up of people from around New Zealand with a broad range of skills, such as biostatistics, infectious diseases, geriatrics, paediatrics, consumer interests, pharmaceutical chemistry and manufacturing, clinical pharmacology, toxicology, clinical genetics, rheumatology and psychiatry. Their identities aren't public to protect them from external pressure in giving independent, free and frank advice about medicine approvals.

## Has Medsafe shortened its evaluation process?

Medsafe has streamlined its approval processes for faster access, but it hasn't cut any corners along the way. This includes allowing pharmaceutical companies to submit rolling applications for approval for their vaccines, rather than submitting all their data at once.

We have prioritised the COVID-19 vaccines and allocated assessors for each vaccine. We have close communication with the pharmaceutical companies about the timelines for getting their data and we've been accepting rolling submissions of data.

We received the first set of data from Pfizer last November. Last week, we received a large amount of data from Pfizer. After assessing it, we've asked them some

questions, for which we've requested a response in a week. Normally we'd give companies four months to respond.

## **Are you concerned about the safety of the vaccine given its fast track development?**

Medsafe has a robust assessment process to ensure this vaccine is safe and effective for use in New Zealand. The development of COVID-19 vaccines around the world has been fast because of enormous financial resourcing, clinical expertise and modern technology has enabled unprecedented swift progress.

## **Are all the logistics in place to store and despatch the vaccine?**

As the largest vaccination campaign in New Zealand's history, it comes with significant challenges.

We've purchased nine large -80°C freezers that can store more than 1.5 million doses of vaccine. These will become our central storage facility for vaccine that requires ultra-low temperatures, which is the Pfizer and BioNTech vaccine.

The nine freezers are in New Zealand and currently undergoing validation. It is expected this process, which includes commissioning, temperature mapping, failure mode challenges and temperature alarm tests, will take up to four weeks before the freezers are approved.

## **Do you have enough vaccinators trained for the rollout?**

We're planning for an extra 2,000-3,000 full time (or equivalent) vaccinators throughout New Zealand who will be trained and available when needed.

An initial call for expressions of interest has gone out via the COVID-19 surge workforce webpage, and we are working with partners across the health and disability system (including regulatory authorities for the relevant healthcare professions and occupational health providers) to engage additional vaccinator capacity across New Zealand.

So far more than 1,100 people have registered their interest in being involved. In addition, more than 2,000 people have been trained as provisional vaccinators, ready to complete the COVID-19 vaccine training once available.

The Ministry of Health has contracted the Immunisation Advisory Centre to provide training on COVID-19 vaccines. This training is expected to begin in February — initially for those vaccinators who will deliver the Pfizer vaccine and then for nurses, doctors and pharmacists. This training will be available online and face to face across the country.

## How will we safeguard Māori?

Under the no/low transmission scenario, the best protection for everyone in New Zealand is to protect those who are most at risk of infection and their household contacts.

We are also reviewing the evidence for additional risk faced by Māori and Pacific peoples in relation to infection and transmission, more serious illness and death, and cultural, social and economic impacts.

We will engage with key stakeholders and consider this alongside implementation options to determine the best approach.

## What are the side effects of this vaccine?

Clinical data from the Pfizer and BioNTech trials shows some minor side effects include a painful arm and headaches. Data we have received at this stage doesn't suggest anything out of the ordinary. This conclusion comes from data provided by Pfizer and information supplied by international regulators we work with like the United States' FDA, the European Medicines Agency, and Australia's regulator the TGA.

There have been reports in other countries of other side effects. We are constantly receiving information from other regulators. We encourage people to report any side effects so Medsafe can determine if they are related to the vaccine or are coincidental.

There have been some reports about allergic reactions in other countries. This has helped Medsafe put conditions on the roll-out such as including a wait time after receiving the vaccine and using trained professionals to administer it. As we learn more, we will continually update our advice on who should receive the vaccine. If you have allergies, please check the list of ingredients on the Medsafe website.

## How effective is this vaccine?

Clinical trial data from Pfizer indicates the COVID-19 vaccine has been 95 percent effective when administered to trial participants. The company reports efficacy is consistent across age, gender, race and ethnicity demographics.

## What happens if someone has an adverse reaction?

As with all vaccines and medicines, any adverse reactions will be reported to the Centre for Adverse Reactions Monitoring (CARM). The pharmaceutical company must provide information on adverse reactions globally. Medsafe and their international counterparts share information on any adverse reactions experienced in their countries.

## What level of adverse reaction is deemed acceptable?

Medsafe reviews all reports of adverse reactions and uses this information to inform what actions, if any, are required to be made to the COVID-19 immunisation programme.

## What is New Zealand's view of the European Union's introduction of new export restrictions for COVID-19 vaccines manufactured in the EU?

New Zealand is very concerned by the European Union's introduction of a new export restrictions for COVID-19 vaccines manufactured in the EU. We have raised this through our channels in Brussels and are seeking further information.

The Ministry of Health is checking whether there are any implications for New Zealand's Advance Purchase Agreement vaccine orders.

New Zealand's advance purchase agreements for COVID-19 vaccines include timing for delivery of vaccines and we expect those agreements to be met. It is up to the pharmaceutical companies to meet the agreed timing schedule for delivery.

Vaccine manufacturing relies on global supply chains and it is in all countries' interests to ensure the smooth functioning of these supply chains, and actively facilitate the flow of COVID-19 vaccines and vaccine-related goods.

## Where can I get more information?

The Immunisation Advisory Centre (IMAC) provides independent, factual information based on international and New Zealand scientific research about vaccine-preventable diseases the benefits and risks of immunisation. <https://www.immune.org.nz/>

On the Medsafe website: <https://www.medsafe.govt.nz/COVID-19/covid-landing.asp> and the Ministry of Health website: <https://www.health.govt.nz/covid-vaccine>

## Unite Against Covid 19

Website <https://covid19.govt.nz/health-and-wellbeing/covid-19-vaccines/>  
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# Frequently Asked Questions

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